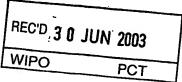


PCT/IL 0 3 / 0 0 3 0 3 17 JUN 2003 10/524077



Ministry of Justice Patent Office

משרד המשפטים לשכת הפטנטים

This is to certify that annexed hereto is a true copy of the as originally different it in the patent applying of which had been applying and the least applying the certification of the least applying and the least applying the least applyin

זאת לתעודה כי רצופים בזה העתקים נכונים של המסמכים שהופקדו לכתחילה עם הבקשה לפטנט לפי הפרטים הרשומים בעמוד הראשון של הנספח.

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

נתאשר Certified

		שימוש הלשכה For Office Us	-
•		152366	: מספר
		10200	Number
			:תאריך
			Date
1	7	-10- 2002	
	",	רחה שששם איי	הוקדםעמ
ł		Ante/P	ost-dates

חוק הפטנטים, התשכ״ז – 1967 PATENTS LAW, 5727-1967

### בקשה לפטנט

**Application for Patent** 

C:45891

אני, (שם המבקש, מענו -- ולגבי גוף מאוגד -- מקום התאגדותו)
I (Name and address of applicant, and, in case of body corporate-place of incorporation)

NEOVASC (2000) LTD. 6 Yoni Netanyahu Street Or Yehuda (An Israeli Company)

נאווסק (2000) בע״מ רחוב יוני נתניהו 6 אור יהודה (חברה ישראלית)

Inventor: Shmuel Ben-Muvhar (An Israeli Citizen)

הממציא: שמואל בן-מובחר (אזרח ישראלי)

ששמה הוא	By Assignment	
Owner, by v		

בעל אמצאה מכח העברה of an invention, the title of which is:

תותב להשתלה בתוך כלי דם

(בעברית)

(Hebrew)

VASCULAR IMPLANT

(באנגלית) (English)

hereby apply for a patent to be granted to me in respect thereof מבקש בזאת כי ינתן לי עליה פטנט \*בקשה חלוקה \*בקשת פטנט מוסף \*דרישה דין קדימה Application for Division Application for Patent of Addition Priority Claim מבקשת פטנט מספר.סימו \*לבקשה/לפטנט וטאריך מדינת האיגוד Number/Mark from Application Date Convention Country to Patent/Appl. dated יום Dated רצוף בזה / עוד יוגש-\*יפוי כח: כללי/מיוחד P.O.A.: general / individual - attached / to be filed later filed in case \_הוגש בענין המען למסירת הודעות ומסמכים בישראל Address for Service in Israel סנפורד ט. קולב ושותי ת.ד 2273 דחובות 76122 חתימת המבקש Signature of Applicant 2002 October שנת היום of the year This בשם המבקש לשימוש הלשכה For Office Use סֹנפורד ט. קולב ושותי C:45891

טופס זה, כשהוא מוטבע בחותם לשכת הפטנטים ומושלם בספר ובתאריך ההגשה, הינו אישור להגשת הבקשה שפרטיה רשומים לעיל.
This form, impressed with the Seal of the Patent Office and indicating the number and date of filing, certifies the filing of the application, the particulars of which are set out above.

Delete whatever is inapplicable מחק את המיותר \*

תותב להשתלה בתוך כלי דם

VASCULAR IMPLANT

NEOVASC (2000) LTD. C: 45891

Inventor: Shmuel Ben-Muvhar

נאווסק (2000) בעיימ

הממציא: שמואל בן-מובחר

### VASCULAR IMPLANT

### FIELD OF THE INVENTION

The present invention relates generally to implantable therapeutic devices, and specifically to intravascular implants.

### BACKGROUND OF THE INVENTION

Stent implants are commonly used in treating arterial stenoses and other unwanted constrictions of body passages. Stents typically comprise a metal coil or mesh. An arterial stent, for example, is threaded through the vascular system to the point of stenosis in an artery. When the stent is in place, it is expanded to force the artery open to the desired diameter.

On the other hand, there are some procedures which stent implants are required to constrict the diameter of a blood vessel. For example, Ruiz describes an endoluminal stent having adjustable constriction in U.S. Patent 6,120,534, whose disclosure is incorporated herein by reference. The stent comprises a deformable mesh having a conical portion and a constricted region, which forms a flow-limiting constriction. The stent is delivered and deployed inside a blood vessel. constricted region of the mesh is then selectively enlarged to adjust the flow impedance in the vessel. Ruiz describes particularly the use of his stent to reduce blood flow in the pulmonary artery, as palliative treatment for infants having complex congenital cardiac malformations.

Other types of constricting stents and applications of such stents are described by Shalev et al. in PCT  $\,$ 

Patent Publication WO 01/72239, whose disclosure is incorporated herein by reference. In particular, this publication describes the use of a flow-reducing implant in the coronary sinus, in order to promote angiogenesis in the heart tissues. The implant is inserted by catheter through a central vein, such as the jugular vein and brought into the coronary sinus. Alternatively, the implant may be installed in one or more of the coronary veins. Once the implant is in place, it is allowed to elastically expand or is plastically expanded using a balloon.

## SUMMARY OF THE INVENTION

Embodiments of the present invention provide a constricting implant that is simple and inexpensive to manufacture, and can be deployed easily in the blood vessels, as well as in other body passages. The implant comprises a pair of generally-cylindrical ring members, which are fixed to a tubular sleeve so as to define a lumen passing through the ring members and the sleeve. The ring members each comprise a framework made of a resilient material, which can be compressed while the implant is inserted into the desired location in the blood vessel, and then expands either elastically or plastically to roughly the full diameter of the vessel. The sleeve comprises a flexible material, fabric. The ring members are positioned longitudinally along the sleeve so that there is a longitudinal gap in between the two ring members. A constricting element is fitted around the sleeve in this gap so as to reduce the diameter of the lumen in between the two ring members to less than the diameter of the vessel.

Thus, when the implant is inserted into the vessel (or other body passage), the ring members expand, along with the portion of the sleeve to which they are fixed. The part of the sleeve in the gap between the members, however, remains constricted due to constricting element. This constricted area of the lumen typically reduces the flow of blood through the vessel. The implant is particularly useful for restricting blood flow in the coronary sinus, as described in the abovementioned PCT publication, but it may similarly be used in other veins and arteries, as well as in other medical applications.

There is therefore provided, in accordance with an embodiment of the present invention, a medical implant, including:

first and second ring members, each including a resilient framework having a generally cylindrical form;

a tubular sleeve, fixed to the first and second ring members so as to hold the ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members; and

a constricting element, which is fit around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location.

The framework may include a wire, which is bent in a serpentine form. Typically, the ring members are adapted to be inserted in a radially-compressed form through a body passage to a target position within the passage, and then to expand radially at the target position so as to open the lumen therethrough. The framework may include an elastic material, which is compressible to provide the radially-compressed form of the ring members, and which expands radially when released at the target position.

In one embodiment, the implant includes one or more longitudinal support members, fixed to the framework of the first and second ring members, alongside the sleeve, so as to join the first and second ring members together.

In a further embodiment, the sleeve includes a fabric, which is stitched to the framework of the first and second ring members.

In another embodiment, the lumen passing through the first and second ring members has first and second ends, and the framework is configured to provide elongate

protrusions at one or more of the ends of the lumen. The sleeve may be cut at one or more of the first and second ends in conformance with the protrusions. For example, the sleeve may be cut at the first end in conformance with the protrusions, while the sleeve at the second end covers both the protrusions and interstices between the protrusions at the second end of the lumen.

The implant may be adapted to be implanted in a coronary sinus of a patient, so that a flow of blood through the coronary sinus is inhibited by the reduced diameter of the lumen.

There is also provided, in accordance with an embodiment of the present invention, a method for producing a medical implant, including:

providing first and second ring members, each including a resilient framework having a generally cylindrical form;

fixing a tubular sleeve to the first and second ring members so as to hold the ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members; and

fitting a constricting element around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location.

There is additionally provided, in accordance with an embodiment of the present invention, a method for restricting flow of a fluid through a body passage, including:

providing an implant including first and second ring members, each including a resilient framework having a generally cylindrical form, with a tubular sleeve, fixed to the first and second ring members so as to hold the

ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members, and a constricting element fit around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location;

passing the implant, in a radially-compressed form, through the body passage to a target position within the body passage; and

causing the implant to expand radially at the target position so as to open the lumen therethrough.

Typically, passing the implant includes enclosing the implant within a catheter, which passes through the body passage, and causing the implant to expand includes ejecting the implant through an aperture in a distal end of the catheter. In some embodiments, the distal end of the catheter has generally conical shape, and ejecting the implant includes expanding the distal end so as to the aperture so that the implant may therethrough. Alternatively, ejecting the implant includes tearing the distal end so as to open the aperture so that the implant may pass therethrough. Further alternatively, the distal end of the catheter includes an elastic plug, which closes the aperture while catheter passes through the body passage, ejecting the implant includes radially compressing the plug so as to open the aperture and to allow the lumen of the implant to pass over the plug.

There is further provided, in accordance with an embodiment of the present invention, apparatus for delivery of an implant to a target position in a body passage, the apparatus including:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end made of an elastic material in a generally conical shape with an aperture formed therein; and

an ejector, which is adapted to force the implant in a distal direction, thus stretching the elastic material so as to expand the aperture, whereby the implant passes through the aperture.

There is moreover provided, in accordance with an embodiment of the present invention, apparatus for delivery of an implant to a target position in a body passage, the apparatus including:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end having a generally conical shape with an aperture formed therein; and

an ejector, which is adapted to force the implant in a distal direction, thus causing the distal end of the sheath to tear so as to expand the aperture, whereby the implant passes through the aperture.

The distal end of the sheath may be scored with lines, along which the sheath tears.

There is furthermore provided, in accordance with an embodiment of the present invention, apparatus for delivery of an implant to a target position in a body passage, the apparatus including:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein

the sheath has a distal end with an aperture formed therein;

a lumen passing longitudinally through the sheath and through the implant contained within the sheath, such that a portion of the lumen at the distal end of the sheath is distended so as to plug the aperture while the sheath passes through the body passage, the distended portion of the lumen including a flexible material; and

an ejector, which is adapted to force the implant in a distal direction, thus ejecting the implant through the aperture and compressing the distended portion of the lumen, so that the implant passes over the lumen to the target position in the body passage.

There is also provided, in accordance with an embodiment of the present invention, apparatus for narrowing a body passage, the apparatus including:

a narrowing implant, which includes:

first and second ring members, each including a resilient framework having a generally cylindrical form;

a tubular sleeve, fixed to the first and second ring members so as to hold the ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members; and

a constricting element, which is fit around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location; and

a catheter for delivering the implant to a target position in the body passage.

The present invention will be more fully understood from the following detailed. description of the

embodiments thereof, taken together with the drawings in which:

# BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic, pictorial view of an implantable device for restricting flow in a blood vessel, in accordance with an embodiment of the present invention;

Fig. 2 is a schematic, cross-sectional view of the device of Fig. 1, taken along a line II-II;

Fig. 3 is a schematic side view of the device of Fig. 1 implanted in a blood vessel;

Fig. 4 is a schematic side view of a device for restricting flow, implanted in a blood vessel, in accordance with another embodiment of the present invention;

Fig. 5 is a schematic, pictorial view of an implantable device for restricting flow in a blood vessel, in accordance with still another embodiment of the present invention;

Figs. 6A and 6B are schematic side views of a catheter used to deliver an implantable device to a target location in a blood vessel, in accordance with an embodiment of the present invention;

Figs. 7A and 7B are schematic side views of a catheter used to deliver an implantable device to a target location in a blood vessel, in accordance with another embodiment of the present invention; and

Figs. 8A, 8B and 8C are schematic side views of a catheter used to deliver an implantable device to a target location in a blood vessel, in accordance with yet another embodiment of the present invention.

45891s1

# DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Figs. 1 and 2, which schematically illustrate a device 20 for implantation in a body passage, in accordance with an embodiment of the present invention. Fig. 1 is a pictorial illustration of the device, while Fig. 2 is a cross-sectional view taken along a line II-II in Fig. 1. Device 20 is adapted for use particularly in restricting blood flow through the coronary sinus, as described in the above-mentioned PCT Publication WO 01/72239. Alternatively, devices accordance with the principles of the present invention may be implanted elsewhere in the vascular system, well as in other body passages. For the sake of simplicity and clarity, however, and not limitation, embodiments of the present invention are described hereinbelow with reference to implantation of constricting devices in blood vessels, such as coronary sinus.

Device 20 comprises ring elements 22 and 24, each of which comprises a resilient framework 26. Each framework defines a generally-cylindrical shape, although this shape is distorted by the mechanical constraints of the device, as described below. Therefore, the cylinders tend to widen at the ends of device 20 and narrow toward the middle, as shown in Fig. 1. In the pictured embodiments, framework 26 comprises a wire or thin rod, which is bent into a serpentine shape. Typically, the framework comprises an elastic material, which may be compressed or otherwise bent, but then returns to its original shape, as shown in the figure. Super-elastic materials, such as Nitinol, are useful for this purpose. Alternatively, the framework may comprise a resilient,

deformable material, such as a suitable metal or plastic. Further alternatively or additionally, each framework 26 may comprise a mesh or coil, as is known in the art. In any case, the term "resilient" as used herein means that once device 20 is deployed within a body passage, framework 26 has sufficient mechanical strength to withstand normal forces exerted by the wall of the passage and by fluid flow within the passage, in the manner of stents known in the art.

Ring elements 22 and 24 are fixed to a flexible sleeve 28, which has a generally tubular Typically, sleeve 28 comprises a biocompatible fabric, such as Gore-Tex or Dacron, which is stitched or otherwise fastened to framework 26. Alternatively, other sleeve materials may be used, such as thin plastic or rubber materials. The sleeve is fixed to the ring elements in such a way as to form a lumen 32 (Fig. 2) through device 20. The sleeve is supported at each end of the lumen by one of the ring elements, while leaving a longitudinal gap in sleeve, typically the millimeters long, between the inner ends of the two ring While the ring elements themselves relatively stiff (due to the resilience of framework 26), device 20 can be bent and deformed freely within the gap region of the sleeve.

A constricting element 30 is fitted around sleeve 28 within the gap region. As can be seen in Fig. 2, the effect of this constricting element is to reduce the diameter of lumen 32 to a predetermined size, less than the expanded diameter of ring elements 22 and 24. Constricting element 30 may simply comprise a thread,

which is tied around the sleeve, or it may alternatively comprise a closed ring, made of plastic or metal.

Fig. 3 is a schematic side view of device 20 after implantation inside a blood vessel 40. Typically, device passed through the vascular system to appropriate location (such as the coronary sinus), using suitable percutaneous catheter (not shown in figures). Suitable methods of catheterization for this purpose are known in the art. During the insertion procedure, device 20 is compressed radially, so that its outer diameter is substantially smaller than the blood vessels through which it must pass. As noted above, device 20 is able to bend freely in the area of the gap between ring elements 22 and 24, where constricting element 30 is located. This bending capability generally makes it easier for the physician operating the catheter to pass the device through bends in the blood vessels.

Upon reaching the desired location in blood vessel device 20 released from the catheter. is framework 26 is made of an elastic material, such as Nitinol, the device will expand by itself, due to its own elasticity, as soon as it is released. Alternatively, if framework 26 comprises a malleable material, a balloon may be inflated within each of ring elements 22 and 24, or other means known in the art may be used, in order to expand the framework. The above-mentioned publication describes special types of balloons that may be used for this purpose. As can be seen in Figs. 1 and 3, the serpentine shape of framework 26 creates elongated "fingers" that protrude at the ends of device 20. the ring elements have expanded, these fingers press outward against the wall of the blood vessel,

anchoring device 20 in place. Blood in vessel 40 flows through lumen 32, but flow is restricted by the constriction at constricting element 30. If device 20 is deployed in the coronary sinus, for example, the flow restriction causes increased pressure in the coronary veins, thus promoting myocardial angiogenesis.

Device 20 may be left in place indefinitely, in substantially the form shown in Fig. 3. Alternatively, it may be desirable in some cases to eliminate the flow restriction caused by the device. In such cases, it is not necessary to remove device 20 from the body. Rather, a catheter with a suitable cutting tool may be inserted percutaneously to the location of the device, and the cutting tool may then be used to cut constricting element 30. The constriction in the diameter of lumen 32 will then open up by itself.

Fig. 4 is a schematic side view of an implantable device 50 after implantation inside blood vessel 40, in accordance with another embodiment of the invention. Blood in vessel 40 is assumed to flow from left to right in the view of the figure. Device 50 is substantially identical to device 20, as described above, except for the shape of sleeve 28. In device 20, sleeve 28 is trimmed so that the ends of the sleeve have the same general shape as the "fingers" of framework 26. device 50, however, sleeve 28 is trimmed to a generally straight edge at the upstream (left) end of the device, covering the interstices between the fingers, as well as the fingers themselves. The straight upstream edge can be useful in reducing blood leakage around the sides of the device, thus providing more complete and reliable flow restriction. The uneven shape of the sleeve is

maintained on the downstream edge, in order to anchor device 50 securely to the walls of vessel 40 against the pressure exerted by the blood flow in the vessel. Alternatively, sleeve 28 may be cut in other configurations, as mandated by medical and mechanical considerations.

Fig. 5 is schematic, pictorial a view implantable device 60, in accordance with still another embodiment of the present invention. Device 60 is also substantially similar to device 20, as described above, except for the addition of longitudinal support members 62 and 65. The support members join ring elements 22 and 24 together and thus enhance the mechanical strength and stability of device 60. Although two longitudinal support members are shown in Fig. 5, greater or smaller numbers of supports members may be used in like fashion. Note, however, that in the gap between the ring elements, sleeve 28 is detached from the support members, so that the diameter of lumen 32 can still be reduced by constricting element 30.

Figs. 6A and 6B are schematic side views of a catheter 70, in a cutaway view, which is used to deliver device 20 to a target position in blood vessel 40, in accordance with an embodiment of the present invention. As shown in Fig. 6A, catheter 70 has a tubular outer shell 72 and a central lumen 74. Prior to delivery, device 20 is held inside shell 70, with lumen 74 passing through lumen 32 of device 20. A distal end 76 of shell 72 has a roughly conical shape, and has a small exit aperture 78 surrounding lumen 32.

Typically, to implant device 20 in vessel 40, an operator threads a guide wire 80 through a part of the

patient's vascular system to the target position, as is known in the art. For example, the guide wire may be passed through the jugular vein into the coronary sinus. Once the guide wire is in place, the operator slides lumen 74 over the guide wire, and thus guides distal end 76 of catheter 70 to the target position. A contrast medium may be injected through lumen 74 or through another, parallel lumen (not shown) to aid the operator in visualizing vessel 40 during the procedure using a fluoroscope, as is known in the art.

When distal end 76 has reached the target position, the operator uses an ejector 82 to push device 20 out through aperture 78 in the distal end of the catheter. Distal end 76 in this embodiment is made of a material that is sufficiently elastic so that the aperture opens freely to the diameter of device 20. Once the device is ejected, it expands to the diameter of vessel 40, as shown in Fig. 3, and anchors itself in place. The operator then withdraws catheter 70, and distal end 76 contracts back roughly to its original form.

Figs. 7A and 7B are schematic side views of another catheter 90, which is used to deliver device 20, in accordance with an alternative embodiment of the present invention. Fig. 7A shows the catheter before delivery of device 20, while Fig. 7B shows the catheter after the delivery. In this embodiment, distal end 76 comprises a thin sheath, which tears open as ejector 82 pushes the device out of the catheter. Optionally, as shown in Fig. 7A, the distal end is scored along lines 92, so that as device 20 is ejected, the distal end tears cleanly, in a predictable fashion. Once device 20 has been ejected, the distal end may remain open where it has torn, but the

open distal does not interfere with withdrawal of catheter 90 along wire 80.

Figs. 8A, 8B and 8C are schematic side views of a catheter 100 for delivering device 20, in accordance with yet another embodiment of the present invention. In this embodiment, distal end 76 has an aperture 102 that is large enough to accommodate the (compressed) diameter of device 20 when the device is ejected from the catheter. Until the catheter reaches the target position, however, the aperture is closed by a distended portion 104 of a lumen 106 that passes through the catheter, as shown in Fig. 8A. The lumen is typically used to accommodate a guide wire and/or to inject contrast medium, as described above. Distended portion 104 is made of a flexible material, which may be either elastic or malleable, and is shaped so as to plug aperture 102.

When distal end 76 reaches the target position, lumen 106 is advanced (and/or catheter 100 is withdrawn) so as to open aperture 102, as shown in Fig. 8B. Ejector 82 then pushes device 20 out through the aperture. As shown in Fig. 8C, portion 104 is sufficiently flexible so that as the narrow, gap region of lumen 32 through device 20 passes over it, portion 104 closes down so that lumen 32 can slide over it. Once device 20 has been implanted at the target position, portion 104 resumes its previous shape, and lumen 106 may be pulled back in the proximal direction in order to close aperture 102. Catheter 100 is then withdrawn from the body.

Although in the embodiments described above, framework 26 and sleeve 28 are shown to have certain particular shapes, alternative shapes and forms of these elements, which will be apparent to those skilled in the

art, are considered to be within the scope of the present invention. Similarly, catheters of the general types described above may be used to deliver not only device 20, but also other implantable devices as described hereinabove and as are otherwise known in the art. On the other hand, although the catheters shown here provide convenient means for delivering implants in accordance with the present invention, such implants may also be delivered by other means, both minimally invasive (typically percutaneous) and invasive (i.e., surgical).

It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has particularly shown and described hereinabove. scope of the present invention includes combinations and subcombinations of the various features described hereinabove, as well as variations modifications thereof which would occur to skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

#### CLAIMS

A medical implant, comprising:

first and second ring members, each comprising a resilient framework having a generally cylindrical form;

a tubular sleeve, fixed to the first and second ring members so as to hold the ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members; and

a constricting element, which is fit around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location.

- 2. An implant according to claim 1, wherein the framework comprises a wire, which is bent in a serpentine form.
- 3. An implant according to claim 1, wherein the ring members are adapted to be inserted in a radially-compressed form through a body passage to a target position within the passage, and then to expand radially at the target position so as to open the lumen therethrough.
- 4. An implant according to claim 3, wherein the framework comprises an elastic material, which is compressible to provide the radially-compressed form of the ring members, and which expands radially when released at the target position.
- 5. An implant according to claim 1, and comprising one or more longitudinal support members, fixed to the framework of the first and second ring members, alongside

the sleeve, so as to join the first and second ring members together.

- 6. An implant according to claim 1, wherein the sleeve comprises a fabric.
- 7. An implant according to claim 6, wherein the fabric is stitched to the framework of the first and second ring members.
- 8. An implant according to claim 1, wherein the lumen passing through the first and second ring members has first and second ends, and wherein the framework is configured to provide elongate protrusions at one or more of the ends of the lumen.
- 9. An implant according to claim 8, wherein the sleeve is cut at one or more of the first and second ends in conformance with the protrusions.
- 10. An implant according to claim 9, wherein the sleeve is cut at the first end in conformance with the protrusions, while the sleeve at the second end covers both the protrusions and interstices between the protrusions at the second end of the lumen.
- 11. An implant according to claim 1, wherein the implant is adapted to be implanted in a coronary sinus of a patient, so that a flow of blood through the coronary sinus is inhibited by the reduced diameter of the lumen.
- 12. A method for producing a medical implant, comprising:

providing first and second ring members, each comprising a resilient framework having a generally cylindrical form;

fixing a tubular sleeve to the first and second ring members so as to hold the ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members; and

fitting a constricting element around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location.

- 13. A method according to claim 12, wherein providing the framework comprises bending a wire into a serpentine form.
- 14. A method according to claim 13, wherein the lumen passing through the first and second ring members has first and second ends, and wherein bending the wire comprises producing elongate protrusions of the framework at one or more of the ends of the lumen.
- 15. A method according to claim 12, and comprising fixing one or more longitudinal support members to the framework of the first and second ring members, alongside the sleeve, so as to join the first and second ring members together.
- 16. A method according to claim 12, wherein fixing the sleeve comprises stitching a fabric to the framework of the first and second ring members.
- 17. A method for restricting flow of a fluid through a body passage, comprising:

providing an implant comprising first and second ring members, each comprising a resilient framework having a generally cylindrical form, with a tubular sleeve, fixed to the first and second ring members so as to hold the ring members in mutual longitudinal

alignment, thereby defining a lumen passing through the ring members, and a constricting element fit around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location;

passing the implant, in a radially-compressed form, through the body passage to a target position within the body passage; and

causing the implant to expand radially at the target position so as to open the lumen therethrough.

- 18. A method according to claim 17, wherein the framework comprises an elastic material, which compressible to provide the radially-compressed form, and expands radially when released at which the position.
- 19. A method according to claim 17, wherein the lumen passing through the first and second ring members has first and second ends, and wherein the framework is configured to provide elongate protrusions at one or more of the ends of the lumen, and wherein causing the implant to expand comprises anchoring the implant in the target position using the elongate protrusions.
- 20. A method according to claim 17, wherein the body passage is a coronary sinus of a patient, and wherein the implant inhibits a flow of blood through the coronary sinus due to the reduced diameter of the lumen.
- 21. A method according to claim 17, wherein passing the implant comprises enclosing the implant within a catheter, which passes through the body passage, and wherein causing the implant to expand comprises ejecting

the implant through an aperture in a distal end of the catheter.

- 22. A method according to claim 21, wherein the distal end of the catheter has generally conical shape, and wherein ejecting the implant comprises expanding the distal end so as to open the aperture so that the implant may pass therethrough.
- 23. A method according to claim 21, wherein the distal end of the catheter has generally conical shape, and wherein ejecting the implant comprises tearing the distal end so as to open the aperture so that the implant may pass therethrough.
- 24. A method according to claim 21, wherein the distal end of the catheter comprises an elastic plug, which closes the aperture while the catheter passes through the body passage, and wherein ejecting the implant comprises radially compressing the plug so as to open the aperture and to allow the lumen of the implant to pass over the plug.
- 25. Apparatus for delivery of an implant to a target position in a body passage, the apparatus comprising:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end made of an elastic material in a generally conical shape with an aperture formed therein; and

an ejector, which is adapted to force the implant in a distal direction, thus stretching the elastic material so as to expand the aperture, whereby the implant passes through the aperture.

26. Apparatus for delivery of an implant to a target position in a body passage, the apparatus comprising:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end having a generally conical shape with an aperture formed therein; and

an ejector, which is adapted to force the implant in a distal direction, thus causing the distal end of the sheath to tear so as to expand the aperture, whereby the implant passes through the aperture.

- 27. Apparatus according to claim 26, wherein the distal end of the sheath is scored with lines, along which the sheath tears.
- 28. Apparatus for delivery of an implant to a target position in a body passage, the apparatus comprising:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end with an aperture formed therein;

a lumen passing longitudinally through the sheath and through the implant contained within the sheath, such that a portion of the lumen at the distal end of the sheath is distended so as to plug the aperture while the sheath passes through the body passage, the distended portion of the lumen comprising a flexible material; and

an ejector, which is adapted to force the implant in a distal direction, thus ejecting the implant through the aperture and compressing the distended portion of the lumen, so that the implant passes over the lumen to the target position in the body passage.

29. Apparatus for narrowing a body passage, the apparatus comprising:

a narrowing implant, which comprises:

first and second ring members, each comprising a resilient framework having a generally cylindrical form;

a tubular sleeve, fixed to the first and second ring members so as to hold the ring members in mutual longitudinal alignment, thereby defining a lumen passing through the ring members; and

a constricting element, which is fit around the sleeve at a location intermediate the first and second ring members so as to reduce a diameter of the lumen at the location; and

a catheter for delivering the implant to a target position in the body passage.

30. Apparatus according to claim 29, wherein the catheter comprises:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end having a generally conical shape with an aperture formed therein; and

an ejector, which is adapted to force the implant in a distal direction, thus stretching the elastic material so as to expand the aperture, whereby the implant passes through the aperture and is implanted at the target position.

31. Apparatus according to claim 29, wherein the catheter comprises:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end having a generally conical shape with an aperture formed therein; and

an ejector, which is adapted to force the implant in a distal direction, thus causing the distal end of the sheath to tear so as to expand the aperture, whereby the implant passes through the aperture and is implanted at the target position.

32. Apparatus according to claim 29, wherein the catheter comprises:

an elongate, tubular sheath, which is adapted to be passed through the body passage while containing the implant in a compressed state inside the sheath, wherein the sheath has a distal end with an aperture formed therein:

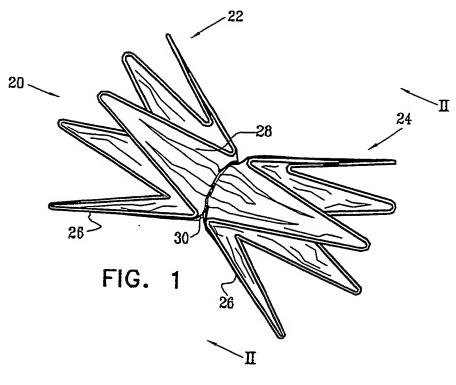
a lumen passing longitudinally through the sheath and through the implant contained within the sheath, such that a portion of the lumen at the distal end of the sheath is distended so as to plug the aperture while the sheath passes through the body passage, the distended portion of the lumen comprising a flexible material; and

an ejector, which is adapted to force the implant in a distal direction, thus ejecting the implant through the aperture and compressing the distended portion of the lumen, so that the implant passes over the lumen to the target position in the body passage.

For the applicant,

Sanford T. Colb & Co.

C: 45891



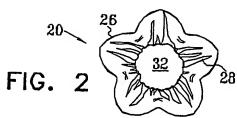


FIG. 3

20

28

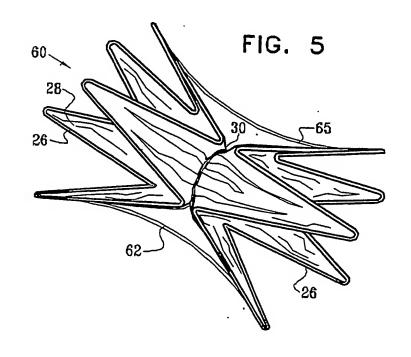
28

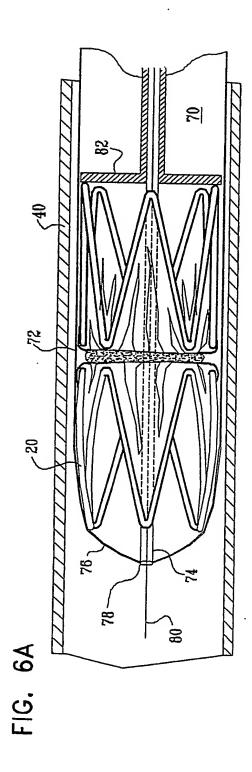
30

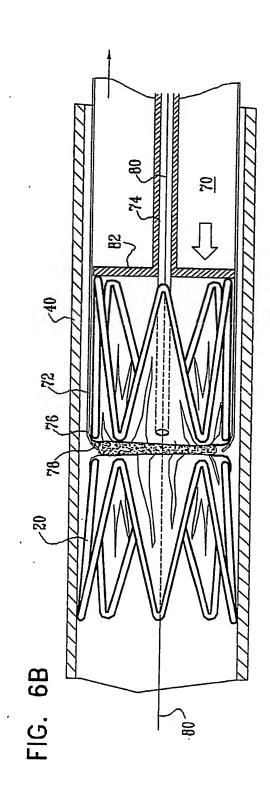
40>

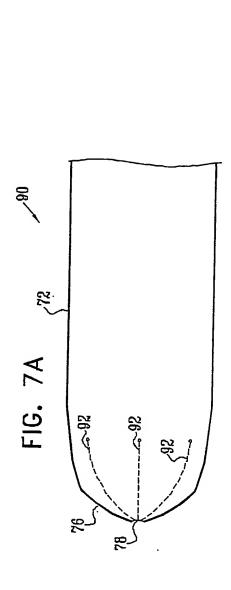
FIG. 4

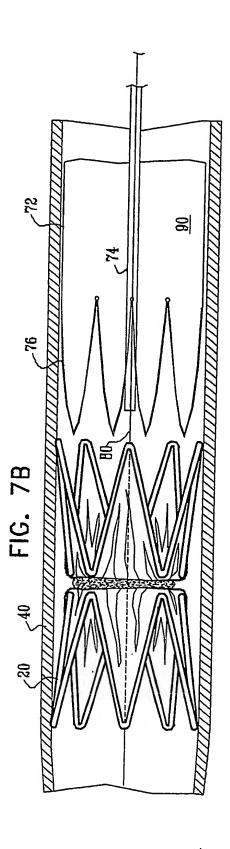
 $\leq_{30}$ 

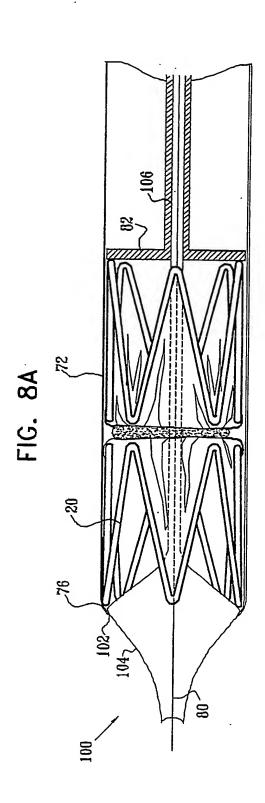


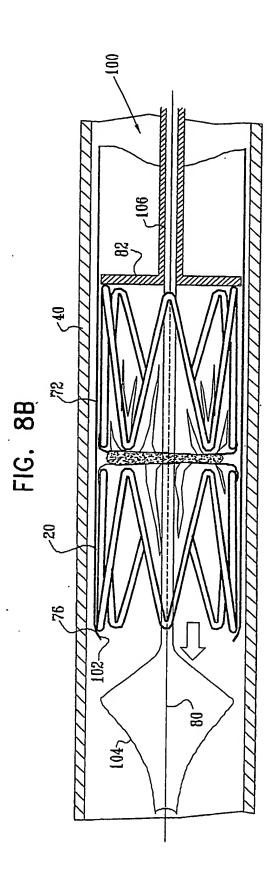












# This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

### **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

Defects in the images menute out are not innited to the items encered.		
☐ BLACK BORDERS		
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES		
☐ FADED TEXT OR DRAWING		
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING		
☐ SKEWED/SLANTED IMAGES		
☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS		
GRAY SCALE DOCUMENTS		
☐ LINES OR MARKS ON ORIGINAL DOCUMENT		
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY		

### IMAGES ARE BEST AVAILABLE COPY.

☐ OTHER:

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.